

REMARKS

Claims 31-60 are canceled, without prejudice, from this application and that subject matter is rewritten as new claims 61-86. New claims 61-73 essentially recite the subject matter of previous claims 31-37, 41-44 and 46-49 but are rewritten in a form to more precisely define metes and bounds of the inventive aspects of this application. New claims 74-86 essentially recite the subject matter of claims 38-40, 45, and 50-59 which are currently withdrawn from consideration. However, in view of this the above amendments and the following remarks, all of the withdrawn claims are now believed to be in a form suitable for examination by the Examiner.

Claims 31-37, 41-44 and 46-49 are first rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons noted in the official action. The subject matter of the rejected claims is accordingly revised and rewritten as new claims 61-86, and all of the presently pending claims are now believed to particularly point out and distinctly claim the subject matter regarded as the invention, thereby overcoming all of the raised § 112, second paragraph, rejections. The entered claim amendments are directed solely at overcoming the raised indefiniteness rejection(s) and are not directed at distinguishing the present invention from the art of record in this case.

Claims 31-36, 41-43 and 46-48 are rejected, under 35 U.S.C. § 102(b), as being anticipated by Bader WO 01/09282, as translated for U.S. National Stage Application No. 10/048,440 ("Bader '282"). The Applicant acknowledges and respectfully traverses the raised anticipatory rejection in view of the following remarks.

Initially, the following brief discussion is provided concerning the present invention. As set forth throughout the specification, the present invention is directed to a bioreactor which can be formed into a variety of complex shapes and/or sizes. This is achieved by having an external boundary layer which is impermeable to the living cells and the external boundary layer

precisely defines the shape and the size of the cell culture chamber. As a result of this improvement, the support structure can be formed exactly into an implant and/or prosthesis of virtually any desired shape and/or size.

Once the support structure is formed and then furnished with a boundary layer, the cells are introduced into the support structure. The support structure is typically formed from a microporous or a coarsely porous material--the support structure may be a removable or a convertible place holder material so that the cell layer may be formed in accordance with the desired shape and/or size of the implant and/or the prosthesis. By using a computer tomogram, for example, a defective vertebra may be identified and the defect vertebra may then be accurately reproduced into the shape of a support structure. By having an accurately shaped and sized support structure, e.g., the defective vertebra, this more readily facilitates production of a replacement vertebra, for the defective vertebra, and the replacement vertebra can then be surgically inserted in place upon removal of the defective vertebra.

Turning now to the applied art of Bader '282, this reference relates to a device for culturing and/or treating cells. The device has a cell culture area which is formed on one side by a support 1 and on the other side by a cell culture film 2. Cells are injected between a carrier film 3 and the culture film 2 and are fed nutrients and cultured. The culture film 2, however, is *elastic* and this allows the cell layer to grow while still being maintained within the cell culture area. In view of the elastic culture film 2 specifically disclosed by Bader '282, Bader '282 is not believed to in any way teach, suggest or disclose shaping a material, inert to living cells, into a porous support structure having a shape and a size corresponding to a shape and size of a human body part to be replaced and following formation of the implant or the prosthesis, applying a boundary layer of material impervious to the living cells to the porous support structure; and removing the boundary layer so as to thereby result in an implant or a

prosthesis having a shape and a size which corresponds to the shape and the size of the human body part to be replaced, as presently claimed.

Claims 31-32, 35-36, 42, 46 and 49 are rejected, under 35 U.S.C. § 102(b), as being anticipated by Kleinman (Current Protocols in Cell Biology, 1998). The Applicant acknowledges and respectfully traverses this raised anticipatory rejection in view of the following remarks.

Kleinman relates to a preparation of gelled substrates which may be used for cell culture. As taught, the substrates are prepared in culture dishes and then "add cells and medium as usual and culture" (see Kleinman, page 10.3.2, 3a). The Applicant does not believe the disclosure of Kleinman in any way anticipates the presently claimed method and/or apparatus of forming one of an implant or a prosthesis into the shape and the size of the human body part to be replaced, as presently recited.

Claims 31, 35-37 and 42 are rejected, under 35 U.S.C. § 102(b), as being anticipated by Schinstine et al. '747. The Applicant acknowledges and respectfully traverses this raised anticipatory rejection in view of the following remarks.

Schinstine '747 relates to a method for modification of cells that are encapsulated within the bioartificial organ and a method for modifying the growth surfaces within the bioartificial organ. The Applicant does not believe this disclosure of Schinstine '747 in any way anticipates the presently claimed method and/or apparatus of forming one of an implant or a prosthesis to the shape and the size of the human body part to be replaced, as presently recited.

In order to emphasize the above noted distinctions between the presently claimed invention and the applied art, the independent claims of this application now recite the features of

forming a material, inert to living cells, into a porous support structure and at least one of shaping and sizing the porous support structure into one of an implant and a prosthesis having a shape and a size corresponding to a shape

and size of a human body part to be replaced; applying a boundary layer of material impervious to the living cells to the porous support structure . . . following formation of one of the implant and the prosthesis, removing the boundary layer and thereby resulting in one of the implant and the prosthesis formed from the porous support structure and the living cells in which one of the implant and the prosthesis has the shape and the size which corresponds to the shape and the size of the human body part to be replaced.

Such features are believed to clearly and patentably distinguish the presently claimed invention from all of the art of record, including the applied art.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejections should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejection(s) or applicability of the Bader '282, Kleinmann and/or Schinstine et al. '747 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,



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